



May 29, 2018

Tom Sinks  
Office of the Science Advisor  
U.S. Environmental Protection Agency  
1200 Pennsylvania Avenue Northwest  
Washington, DC 20460

*Submitted under Docket ID No. EPA-HQ-OA-2018-0259 via [www.regulations.gov](http://www.regulations.gov)*

RE: The Minnesota Pollution Control Agency and Minnesota Department of Health's joint comments regarding the U.S. Environmental Protection Agency's proposed rule, "Strengthening Transparency in Regulatory Science", published April 30, 2018, at 83 FR 18768, Docket ID No. EPA-HQ-OA-2018-0259.

Dear Tom Sinks:

The Minnesota Pollution Control Agency (MPCA) and the Minnesota Department of Health (MDH) are deeply disappointed in, and troubled by, the U.S. Environmental Protection Agency's (EPA) proposed rule, "Strengthening Transparency in Regulatory Science", published April 30, 2018, at 83 FR 18768, under Docket ID No. EPA-HQ-OA-2018-0259.

As regulatory agencies whose missions are to protect and improve Minnesota's environment and human health, the MPCA and MDH are deeply troubled by this proposed rule. The rule, seemingly written without the knowledge of career staff at EPA or EPA's existing scientific advisory boards, seems designed to undermine and disparage the important epidemiological studies that support public health protection from all pollutants. Simply stated, the proposal was written with the intent to cast doubt on EPA's prior judgement of, and dependence on, health research – and to create suspicion significant enough to deter future use of health-based studies in regulatory decision making. Privacy of health data is a foundational ethic for the medical and health science research fields, and EPA's proposal ignores the historical context under which the privacy rules around health data were developed.

Attached to this letter is a document (enclosure) outlining, in greater detail, the concerns that MPCA and MDH have regarding both the intent behind the rule, as described in the General Information and Background sections of 83 FR 18768.

The enclosure discusses the following points:

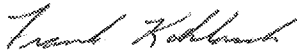
1. EPA provides no rationale regarding the need for, or reasonableness of, this proposal.
2. This proposed rule weakens longstanding privacy protections afforded US citizens.
3. This rule does not integrate, nor does it provide solutions for, the current work on data reproducibility within the scientific community.
4. This rule cannot be implemented within a reasonable timeframe.
5. This proposed rule is counter the current goal of Cooperative Federalism.
6. EPA must withdraw this proposal.

Promulgation of this rule would be a significant departure from EPA's core mission: to protect Americans' health and the environment. It would set a dangerous and potentially life-threatening precedent regarding the use of health-based data, modeling, and research in regulatory decision making. Although intended to "strengthen transparency", the Rule does not provide transparency or clarity at all — rather, it causes confusion and mistrust, and will threaten the lives of real people.

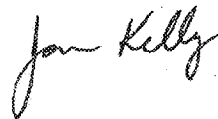
As proposed, the rule is arbitrary, capricious, unethical, and intellectually dishonest. EPA should immediately withdraw this dangerous and ill-conceived proposal.

If there are additional questions related to these comments, please contact Anne Jackson at the MPCA. She can be reached at [anne.jackson@state.mn.us](mailto:anne.jackson@state.mn.us) or at 651-757-2460.

Sincerely,



Frank Kohlasch, Manager  
Air Assessment and Analysis  
Environmental Analysis and Outcomes Division  
Minnesota Pollution Control Agency



James Kelly, M.S., Manager  
Environmental Surveillance & Assessment  
Environmental Health Division  
Minnesota Department of Health

AMJ/FK/JK:vs

Enclosure

cc: E. Scott Pruitt, U.S. Environmental Protection Agency  
Cathy Stepp, U.S. Environmental Protection Agency, Region 5

## **Minnesota's comments on the proposed rule, "Strengthening Transparency in Regulatory Science" (83 FR 18768)**

**Docket ID No. EPA-HQ-OA-2018-0259**

### **Agency support rather than regulatory action is the appropriate vehicle to improve data transparency.**

Minnesota supports open data, and is a national leader in scientific and regulatory transparency. Our agencies are at the forefront of making environmental and health surveillance data publically available, providing technical assistance for using that data, and engaging partners across communities and research institutions around effective data dissemination and utilization. Our agencies host multiple platforms for accessing high-quality health surveillance and environmental monitoring data, while protecting privacy and providing essential risk communication and prevention strategies. Detailed data are similarly available for research uses, under the approval and guidance of state institutional review boards (IRBs).

As regulatory agencies whose missions are to protect and improve Minnesota's environment and human health, the MPCA and MDH are concerned about this proposed rule leading to the censorship of health sciences research and epidemiological findings (see the MPCA's May 15 letter to Administrator Scott Pruitt at the end of this document). These studies are the basis for establishing standards and toxicity values to protect public health.

The proposed rule undermines the important epidemiological studies that support public health protection from all pollutants, be they in the air, water, biota, or soil. Properly implementing this rule will require EPA to first address many legal aspects surrounding public and nonpublic data, significantly expand database tools and peer review capacity, and develop guidelines for the use of "independent validation" – all of which require considerable time and financial resources. As a result, the proposed rule does little to improve the transparency of current work and, in fact, will cloud the conduct and evaluation of health studies and delay the adoption of human health-based pollution standards for the foreseeable future.

The proposal casts doubt on EPA's prior judgement of, and dependence on, health research – and creates suspicion significant enough to interfere with the future use of existing health-based studies in regulatory decision making. More importantly, EPA's proposal flagrantly ignores the historical context and reasons for the privacy of health data used for epidemiological studies. Privacy of health data is a foundational ethic for the medical and health science research fields, upheld by decades of US Supreme Court decisions.

## **EPA provides no rationale regarding the need for, or reasonableness of, this proposal.**

It is appropriate that EPA continues its efforts to make data publically available<sup>1</sup>, to ensure that agency decisions are supported by the best available scientific knowledge and research, and that deliberations are well-reasoned and explained to the public. In the context of this proposal, however, Minnesota is most concerned about the implementation of this rule, and censoring studies from use in EPA work because they could not be “independently validated” because of privacy issues. Such an outcome would result in regulatory records supporting unreliable, pre-determined outcomes or decisions.

The preamble is not clear about the problem this proposed rule will address. EPA states that the proposed rule is designed to “...change agency culture and practices regarding data access so that the scientific justification for regulatory actions is truly available for validation and analysis” (83 FR 18770). Changing agency culture does not occur through rulemaking, especially if few resources are given to new rule implementation. Agency culture and work practices are changed when agency administrators provide leadership, direction, and support of technical and career staff through adequate funding and, in the case of EPA, partnerships with the health and environmental research communities.

This proposed rule’s focus on the epidemiology of dose-response data undermines “pivotal regulatory science”. Although EPA’s argument is that there should be a regulation to ensure increased access to dose-response data and models, EPA offers no evidence of an existing problem with dose-response data transparency that needs to be addressed, nor does EPA demonstrate how independent validation outside of existing peer review processes improves upon current data transparency practices and data availability. EPA offers no evidence that EPA’s previous judgement, particularly in the development of dose-response functions, has been inadequate, invalid, or otherwise arbitrary. Frankly, we view this proposal, and its requirement of making publically available data for “independent validation”, simply as a means of providing industries concerned with various studies an opportunity to reanalyze data to reshape or recast conclusions drawn by researchers and subsequent peer reviews, and to allow EPA to censor important studies without justification.

The proposed rule’s provision to allow the Administrator to provide case-by-case exemptions in Part 30.9 does not resolve our concerns. The rule sets no criteria for the Administrator to censor a study other than whether the data can be made publically available, nor does the rule require the Administrator to explain or justify why a study was censored or used in the regulatory decision. Without expanded criteria or the requirement to describe how or why studies are included or excluded from a regulatory decision, the Administrator would be free to act in an arbitrary manner.

From a risk assessment perspective, excluding epidemiological studies in regulatory science is not sound or prudent. Laboratory work, toxicological research, and epidemiological studies are complementary, and each facet is necessary when it comes to understanding and quantifying the effects of a pollutant on

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<sup>1</sup> EPA has an ongoing program to expand and improve open access for research. <https://www.epa.gov/open>

human health. Eliminating evidence from one of these three essential disciplines threatens the scientific basis for regulatory decisions and actions. The proposed rule would put regulators tasked with protecting human health in the impossible situation of relying primarily on animal or in-vivo models, which cannot be directly extrapolated to human dose-response estimates.

Minnesota, and other states, rely on the EPA to provide us with scientific information that is accurate and sound. If EPA's data begins to depart from being scientifically sound and reliable, the Agency's credibility in protection of human health and environment is diminished. States are left with a data gap that simply cannot be filled with our limited resources. EPA's strong leadership in unbiased scientific research and reasoned application promotes consistency for state agencies across the country, regulatory certainty for businesses, and provides the information, standards and guidelines necessary to provide health protections for US citizens. Minnesota, and others, continue to depend on EPA's leadership.

### **This proposed rule weakens longstanding privacy protections afforded to U.S. Citizens.**

While nothing in the proposed rule compels disclosure of personal identifying information (e.g., name, address), disclosure of analytic data sufficient to fully replicate study analyses would effectively breach confidentiality requirements upheld by public and private research through IRBs. Data availability, as it would be under this rule, would disclose information such as geocoded latitude/longitude residential locations; demographic covariates; and repeated measures in longitudinal population-based studies. If made publicly available, as required by the proposed rule, the specificity of these non-private covariates would facilitate, with relative ease, the re-identification of individuals and their protected health information. Further, it is this very specificity in geographic, demographic, and health information that contribute to epidemiological studies with the most robust quantification of dose-response and uncertainty relationships. It is well documented that privacy assurances are essential to access population health information, recruit and maintain population-based cohorts, and to mitigate non-random selection bias. The proposed rule does not make clear how it would assess or address bias or systematic errors in population studies that were able to release un-masked analytic data to the public.

Ethical and legal frameworks protecting patient and study participant confidentiality are foundational to robust and unbiased analyses; requiring release of these data would effectively bar the most informative population-based studies from contributing to regulatory science. It does not seem that such epidemiological studies could fulfill obligations of IRB-mandated informed consent, patient confidentiality, and Health Insurance Portability and Accountability Act (HIPAA) data governance systems. Not every IRB study is done by a HIPAA covered entity, but nearly every IRB study that involves human health is covered by some legal privacy protections similar to those under HIPAA.

### **This rule does not integrate, nor does it provide solutions for, the current work on data reproducibility within the scientific community.**

EPA points to a "replication crisis" (83 FR 18770) as one possible reason prompting this rule proposal. There are alternative mechanisms for addressing the so-called replication crisis, however, including

peer-review and supervised re-analysis, as well as utilizing or expanding longstanding expert bodies that would not flout, and do not weaken, accepted and effective data privacy systems. These existing, robust mechanisms are also the appropriate locus for discerning appropriateness and adequacy of quantitative models and methods, including non-linearity and effect measure modification of dose-response relationships, as referenced in the proposed rule.

Rather than writing and promulgating a costly rule, the EPA should engage with and support current work that promotes solutions that improve and maintain reproducibility in science. For instance, the list below includes a number of organized discussions by universities, research organizations, and federal agencies to address potential issues surrounding about the problems of reproducibility of scientific studies:

Yale School of Public Health - <https://publichealth.yale.edu/ehs/research/conferences/reproducibility/>,

Keystone Symposia - <https://virtual.keystonesymposia.org/ks/live/39/page/201>,

National Institutes of Health - <https://www.nlm.nih.gov/news/reproducible-research-conference2016.html>,

Society of Toxicology - <http://www.toxicology.org/events/am/AM2016/ss.asp>,

Health Effects Institute - <https://www.healtheffects.org/annual-conference>.

Should EPA believe that more formal and defensible research data practices are needed, it would be more appropriate to follow past practice and request the National Academy of Sciences to develop guidance, similar to its request to develop risk assessment guidance, than to promulgate a new rule.

**This rule is cannot be implemented in a reasonable timeframe.**

We are not certain that this rule can be implemented within a reasonable timeframe, nor is there any evidence that EPA is currently making plans to implement this rule. To that end, if this rule is promulgated, we recommend that any application be only prospective. This rule must not be applied retrospectively; such application would only serve to create confusion with the intent of undermining existing public health regulations.

As the proposed rule offers no instruction as to how or whether EPA use the public's efforts in conducting "independent validation", we recommend that existing EPA programs evaluating human health studies continue under current practices until implementation is completed, including providing sufficient funding for developing open access to databases, establishing guidance as to how and when EPA is to assess or use unsupervised validation studies submitted by the public, as well as determining and resolving public and nonpublic data issues (securing permissions if necessary).

**This proposed rule is counter to the current goal of Cooperative Federalism.**

As an example, the MPCA manages facility air toxics emissions through modeling and risk-based assessments, with support from MDH. Specifically, we compare modeled air concentrations to inhalation health benchmarks. In order to keep our approach systematic and non-biased, the MPCA and MDH pre-select information sources of inhalation health benchmarks in the form of a hierarchy. Approximately 40% of the inhalation health benchmarks that the MPCA uses to manage air toxics

emissions are from EPA's Integrated Risk Information System (IRIS) or Provisional Peer-Reviewed Toxicity Values (PPRTV) programs. Our understanding of this proposed rule leads us to believe that the dose-response information used to develop these values could become mired in redundant and unnecessary review, should the rule be enacted. Any delay in the review of IRIS or PPRTV data greatly compromises the MPCA's ability to assess and appropriately set permit conditions for industries, or to determine clean up requirements for site remediation projects.

The MPCA and MDH do not disagree that it is worth looking at data practices for all research conducted by EPA, and that there may be opportunities for improvement. EPA would be better served making existing data easier to understand, better communicating the scientific research that is being done at the agencies, and how strong partnerships with third parties strengthens EPA's regulatory authority and its public image.

### **EPA must withdraw this proposal.**

EPA claims in this proposal that it does not need to address EO 13045 (protecting children) nor EO 12898 (Environmental Justice in Minority Populations) because "this action does not concern an environmental health risk or safety risk" (83 FR 18773). This is an inaccurate and unsupported claim. The implementation of this rule would indirectly impact the rules and guidelines that are set to protect children, people of color, the elderly, low-income, and other underserved populations.

This action was correctly identified as a "significant regulatory action" under Executive Orders 12866 and 13563, which then requires a regulatory impact analysis (RIA). The RIA would include an estimate of costs of implementing this rule, and an estimate of resulting benefits. EPA claims benefits outweigh costs, but there is no published record or analysis to demonstrate that this claim is valid. This proposed rule is nearly a mirror image of the proposed HONEST Act (H.F. 1430). The Congressional Budget Office was able to estimate an implementation cost for the first two years of rule implementation, at a cost of \$100 million each year<sup>2</sup>. It follows that this proposal would have initial implementation costs of more than \$200 million, while having no benefit.

The intent of this rule is ill-considered, and its potential for implementation is severely limited. EPA asked for input in the public notice that would have been better addressed through an Advanced Notice of Proposed Rulemaking. The record provided with the docket for this proposed rule is nonexistent, and EPA has failed to meet many of the basic requirements in preparing rule proposals for public notice and comment. The rule will likely be determined to be arbitrary and capricious, and is certain to be challenged legally. EPA should withdraw this proposed rule immediately.

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<sup>2</sup> Congressional Budget Office, March 29, 2017. "If the EPA continued to rely on as many scientific studies as it has used in recent years to support its covered actions, then CBO estimates that the agency would need to spend at least \$100 million dollars per year to upgrade the format and availability of those studies' data to the level required by H.R. 1430". <https://www.cbo.gov/publication/52545>





May 15, 2018

The Honorable E. Scott Pruitt, Administrator  
U. S. Environmental Protection Agency  
1200 Pennsylvania Avenue NW  
Mail Code 1101A  
Washington, D.C. 20460

Re: Comments regarding the U.S. Environmental Protection Agency's proposed rule, "Strengthening Transparency in Regulatory Science", published April 30, 2018 at 83 FR 18768, Docket ID No. EPA-HQ-OA-2018-0259

Dear Administrator Pruitt:

The Minnesota Pollution Control Agency (MPCA) and Minnesota Department of Health (MDH) are deeply disappointed in, and troubled by, the U.S. Environmental Protection Agency's (EPA) proposed rule, "Strengthening Transparency in Regulatory Science," published April 30, 2018, at 83 FR 18768, under Docket ID No. EPA-HQ-OA-2018-0259. This proposed rule to "strengthen transparency" does not provide transparency or clarity at all — rather, it causes confusion and mistrust, and it will threaten the lives of real people. EPA should withdraw this dangerous proposal.

As regulatory agencies whose missions are to protect and improve Minnesota's environment and human health, the MPCA and MDH are appalled by the specious and brazen attack on health sciences research and the field of epidemiology. The proposed rule was clearly designed to undermine and disparage the important epidemiological studies that support public health protection from all pollutants, be they in the air, water, or soil. Simply stated, the proposal was written with the intent to cast doubt on EPA's prior judgement of, and dependence on, health research — and to create suspicion significant enough to deter future use of health-based studies in regulatory decision-making. EPA's proposal flagrantly ignores the reasons for the privacy of health data used for epidemiological studies. Privacy of health data is a foundational ethic for the medical and health science research fields.

While nothing in the proposed rule compels disclosure of personal identifying information (e.g., name, address), disclosure of analytic data sufficient to fully replicate study analysis would effectively breach confidentiality requirements upheld by public and private research through Institutional Review Boards (IRB). It is well documented that privacy assurances are essential to including people in health studies.

From a risk assessment perspective, not including epidemiology studies in regulatory science is not sound or prudent. Laboratory, toxicology, and epidemiology are complementary and necessary pieces of understanding and quantifying effects of a pollutant on human health. Excluding evidence from one of these three essential disciplines threatens the science basis for regulatory decisions and actions. The proposed rule would put regulators tasked with protecting human health in an impossible situation of relying primarily on animal models or in-vivo models that cannot be directly extrapolated to human dose-response estimates.

Minnesota supports open data access and is a national leader in science and regulatory transparency. Our agencies are at the forefront of making environmental and health surveillance data available, providing technical assistance for using data, and engaging partners across communities and research institutions

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around effective dissemination and data utilization. Our agencies host multiple platforms for accessing high-quality health surveillance and environmental monitoring data, while protecting privacy and providing essential risk communication and prevention strategies. Detailed data are similarly available for research uses, under the approval and guidance of state IRBs.

Based on the lack of meaningful information and articulated or demonstrated need for the proposed rule, EPA has not made the case for a new regulation at 40 CFR Part 30.

The promulgation of this proposed rule would set a dangerous and potentially life-threatening precedent regarding the use of health-based data, modeling, and research in regulatory decision-making. As proposed, the rule is arbitrary, capricious, unethical, and intellectually dishonest. The EPA should immediately announce that it is withdrawing this proposal.

Our agencies will be submitting additional, substantive comments to the rulemaking record.

Sincerely,



John Linc Stine, Commissioner  
Minnesota Pollution Control Agency  
520 Lafayette Road  
St. Paul, Minnesota 55155



Jan Malcolm, Commissioner  
Minnesota Department of Health  
625 Robert Street North, Box 64975  
St. Paul, Minnesota 55155